Resources for Review of Scientific Data

In anticipation of significant increases in numbers of petitions as FDA expands the scope of health claims to qualified claims for conventional human foods, FDA is setting in place mechanisms for augmenting limited in-house review scientist resources. FDA may pursue any one of several options for scientific review of data submitted in a petition in support of the substance/disease relationship. For example, FDA may conduct the review internally, it may convene an advisory subcommittee, or it may use appropriate third-party reviewers, either individual experts or expert groups, under contract to FDA, e.g., the Agency for Healthcare Quality and Research (AHRQ), as described below.

FDA is developing a mechanism to contract with other federal science agencies or scientific centers to conduct the scientific reviews. For example, FDA has recently developed an interagency agreement (IAG) with AHRQ, in the Department of Health and Human Services (DHHS), to conduct science reviews on a task order basis. AHRQ has an existing contract with 21 Evidence-Based Practice Centers (EPCs) in various university and private research organizations to conduct, on a task order basis, systematic scientific reviews for specified topics. This resource is widely used by other DHHS agencies. For example, various NIH organizational components use the EPCs to conduct literature reviews as background for decisions on whether to fund large-scale intervention trials. The DHHS' U.S. Preventive Services Task Force has routinely used the EPCs to provide systematic reviews as background for recommendations of that Task Force.

EPCs selected through a competitive progress will be assigned to review the scientific evidence for specified substance/disease relationships that are the subject of incoming petitions, prepare reports describing the evidence reviewed, an analysis of that evidence, a summary of and response to public comments that pertain to the evidence, and its assessment as to the degree of scientific certainty in support of the

substances/disease relationship. FDA will review the reports, and any of the evidence and public comments it deems necessary, and make a decision whether to exercise enforcement discretion.

Timeline for Interagency Agreement with AHRQ for external science reviews of qualified health claim petitions

May 29, 2003	Request for Task Order circulated by AHRQ to EPCs
June 20, 2003	Questions regarding Task Order from EPCs due to AHRQ
June 24, 2003	Conference call with FDA, AHRQ, EPCs to discuss questions raised by EPCs regarding the Task Order Request
July 25, 2003	Proposals from EPCs due to AHRQ
August 2003	AHRQ and FDA review proposals and decide on the two EPCs to be chosen
September 1, 2003	Awarding of contracts to two EPCs by AHRQ
Mid-September 2003	Two day meeting in Washington DC with FDA, AHRQ, EPC representatives and selected PHS agency representatives to discuss general framework and criteria for scientific reviews
October 15, 2003	EPCs start reviews of specific qualified health claims topics